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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,928	07/21/2003	Ulrich Posanski	4-20017F	6463

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NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 104/3  
EAST HANOVER, NJ 07936-1080

EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/623,928

Applicant(s)

POSANSKI, ULRICH

Examiner

Blessing M. Fubara

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1618

### **DETAILED ACTION**

Examiner acknowledges receipt of request for Continued Examination filed under 37 CFR 1.114 on 5/24/06. The amendment filed after the final rejection is entered with the filing of the RCE. Claims 11-20 are pending.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/24/06 has been entered.

#### ***Response to Amendment***

Claims 11 and 17 are amended to recite, "consisting essentially of" in place of comprising in line 3 of each claim. The amended claims are further considered and noted that the comprising language (line 1 of each of claim 11 and 17) is open. The "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In the instant case, the composition comprises sparingly soluble therapeutic agent, the sparingly soluble therapeutic agent is solubilised by/with a carrier composition that now consists essentially of sorbitan fatty acid ester co-surfactant, pharmaceutically acceptable oil and non-ionic surfactant. The further

Art Unit: 1618

presence of lipophilic material would not materially affect the basic and novel characteristics of the claimed invention, which is the solubilisation of poorly/sparingly soluble therapeutic agents.

It is noted that oil is lipophilic.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 11-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that application was in possession of the claimed invention. There is no description in the specification for compositions that contain therapeutic agents and the carrier composition now recited in claims 11 and 17.

Claims employing carrier composition that consists essentially of sorbitan fatty acid ester, pharmaceutically acceptable oil and non-ionic surfactant are neither described nor exemplified and the specification does not inform the public of the limits of the monopoly asserted.

Art Unit: 1618

Furthermore, the requirement that the carrier composition consist essentially of sorbitan fatty acid ester, pharmaceutically acceptable oil and non-ionic surfactant raises the issue of new matter since the specification as filed contemplates compositions in which the carrier has propylene glycol, ethanol or dioleate.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauer et al. (US 5,342,625).

Hauer discloses a pharmaceutical composition that comprises cyclosporine, oil, hydrophilic surfactant that has an HLB of greater than 10 and lipophilic surfactant having HLB of less than 10 (column 9, lines 40-47; Examples 1.6-1.10; column 12, lines 35-41) and excess surfactants may be additional carriers and co-solvents as part of the hydrophilic or lipophilic phase (column 12, 42-48). However, while Hauer discloses that sorbitan esters are equally useful as lipophilic surfactants, Hauer does not disclose the specific combination of surfactants. Polyglycerol esters are recognized in the art as lipophilic surfactants (see column 2, lines 2-9 of Reggio et al., US 4,379,169 as a teaching reference). The person of ordinary skill in the art and the skilled artisan have the skills necessary to prepare pharmaceutical compositions by simple mixing of ingredients and such a mixing process would be prima facie obvious.

Art Unit: 1618

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare and use the pharmaceutical composition of Hauer. One having ordinary skill in the art would have been motivated to combine lipophilic and hydrophilic with the expectation of rendering the cyclosporine soluble. Selection of the surfactants from among equally suitable material is proper and obvious, see *Ex parte Winters*, 11 USPQ 2d 1387.

***Response to Arguments***

5. Applicant's arguments filed 5/24/06 have been fully considered but they are not persuasive.

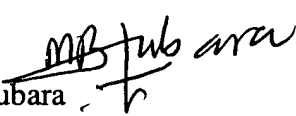
Regarding applicant's assertion that all the examples of Hauer include two types of hydrophilic components, it is noted that the presence of the hydrophilic phase does not materially affect the basic and novel characteristic of the claimed invention. Furthermore, applicant's examples contain cremophor or TWEEN, glycerol fatty acid ester, oil, alpha-tocopherol and ethanol or propylene glycol (Examples 3 and 4) in the carrier composition

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Blessing Fubara  
Patent Examiner  
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